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EXAMINER

HUI, SAN MING R

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/900,647
Filing Date: July 07, 2001
Appellant(s): LOVERCHECK, DALE R.

Dale R. Lovercheck, Esquire
92 Patricia Place,
Media PA 19063
For Appellant

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The rejection of claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87 and 91-94 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,032,384 Yeh et al. 7-1991

SS Pharmaceutical (Comline Biotachnology & Medical, 1 Dec., 1992, page 4)

English abstract of Tsunoda (JP 2000-229853) from JAPIO, Accession number 2000-229853

Krause's Food, Nutrition & Diet therapy, 1992, page 277-279

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The instant claims are directed to a method of indication comprising enclosing the elected species: ibuprofen as discomfort reliever and vitamin C as nutritional supplement in an enclosure and indicating the amounts of the active agents (i.e., ibuprofen and vitamin C) and indications thereof.

The election of species of ibuprofen as discomfort reliever and vitamin C as nutritional supplement was made in response filed May 15, 2002.

Claims 26-30, 33-35, 37-46, 48, 50-54, 56, 59-61, 64-69, 71-84, 86-87, and 91-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over SS Pharmaceutical, Tsunoda and Yeh et al. in view of Krause.

SS Pharmaceutical teaches a composition containing ibuprofen and a high content of vitamin C (See the abstract).

Tsunoda teaches a pain-alleviating tablet containing 300-500mg of ibuprofen and about 30-50mg of vitamin C (See the abstract).

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Yeh et al. teaches a composition containing an antioxidant, such as ascorbic acid, and a NSAID, such as ibuprofen, such that the weight amount of the antioxidant and the NSAID is about 0.01 to 10% of the composition (See particularly the abstract, also col. 2, lines 9 and 48-49; col. 4, line 7-10). Yeh et al. also teaches that the composition can be formulated into oral dosage forms (See particularly col. 3, line 67).

The references do not expressly teach the composition to be labeled as in unit dosage form. The references do not expressly teach the composition to be labeled is in a container enclosure. The references do not expressly teach the composition to be indicated is in an unit form as pill, tablet, or capsule. The references do not expressly teach the composition to be labeled in a container package with a label stating the amount of each ingredients and the indication. The references do not expressly teach a label stating the recommended daily value of nutritional supplement.

Krause teaches that it is mandatory for nutrition manufacturer to list the recommended daily value of vitamin C of the food product on the package label (see page 279, Mandatory Listings of Food Label Section).

Possessing the Examiner's cited prior arts, it would have been obvious to one of ordinary skill in the art at the time the invention was made to label the amount of ibuprofen and vitamin C, as a unit dosage form, in the composition claimed herein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to enclose the ibuprofen-vitamin C unit dose tablet into a container and indicate label the amount of each ingredient: the recommended daily value of the nutritional supplement, and those amounts therein contained.

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One of ordinary skill in the art would have been motivated to indicate the amount of ibuprofen and vitamin C, as a unit dosage form, in the composition claimed herein and place the same into a container with indicator (label) indicating the amount of each ingredients, the recommended daily value of the nutritional supplement, and the old-and-well-known properties these compounds possess. Firstly, employing the herein claimed amount of ibuprofen and vitamin C is considered as optimization of result effect parameters, which is obvious as being within the skill of the artisan, absent evidence to the contrary. Secondly, putting the drug dosage form into a container is considered obvious within the purview of skilled artisan. Thirdly, inclusion of a package insert or label, which is considered as indicator in the instant case, showing the “the name of drug, dosage, dosage form, route of administration, indication and direction of use” of a pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. Finally, title 21 also mandates listing the recommended daily value of a nutritional supplement on the package label. Therefore, a method of labeling of the herein claimed products is considered obvious to one of ordinary skill in the art since labeling the herein claimed information, regardless of the drug is, is mandated by law.

(11) *Response to Argument*

Appellant's arguments in pages 2-5 averring lack of any teaching for the combination of references are not convincing. Appellant specifically argues that because the cited prior art does not intend for vitamin C as nutritional supplement, then

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vitamin C is not a nutritional supplement, and thus, the cited prior arts provides no motivation to include the herein claimed labelling information. Such arguments are flawed because regardless of the use one intends for vitamin C, vitamin C is a well-known nutritional supplement. Examiner notes that products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties appellant discloses and/or claims are necessarily present (See *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)). See MPEP 2112.01. Labelling the contents of a container is conventional regardless what is therein contained. In the case of nutritional supplements and drugs, labelling is reinforced by law, and thus, obvious. Furthermore, the instant claims essentially read on a conventional method of putting vitamin C and ibuprofen in a bottle and labelling the bottle for what it contains inside. As discussed in the previous office action mailed January 28, 2004, the label or the steps of labelling do not bear any patentable weight to the instant claims. Attention is drawn to *In re Miller* 164 USPQ 46 (CCPA1969) and *In re Gulack* 217 USPQ 401 (CAFC) 1983. In *Miller*, the Court relies on the fact that there is a functional relationship between a measuring cup and the indicia (printed material) on the cup. A cup is not a measuring cup without the indicia since one cannot employ the cup (without indicia) to take accurate measurements. In other words, the content of the printed materials bear no patentable weight unless a functional relationship between the label and the actives is found. In the instant case, a patient can take a medication even without having the written instructions at hand. The ultimate function of the instant composition relies not

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on the written instructions, but on the active pharmaceutical ingredient, i.e., ibuprofen and vitamin C, contained therein. The Court in *In re Gulack* also states that "where the printed material is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability.". Here, the proffered set of instructions is not functionally related to the composition because the composition can function as an active and effective drug, even in the absence of the set of instructions (i.e., package insert or indication). Therefore following the reasoning in *Miller* and *Gulack*, we can conclude that the "printed material", i.e., the indication or package insert, does not patentably distinguish the instant claims over the prior art. Therefore, absent a labeling steps, herein claims read on a method of combining the ibuprofen and vitamin C, at the herein claimed amount. Since the cited prior art provide the motivation to combine vitamin C and ibuprofen, the limitations recited in the instant claims are seen to be met by the teachings of the cited prior art.

Appellant also argues unconvincingly that minerals such as calcium, magnesium and iron are not often labeled. As discussed in the paragraphs above and in office action mailed January 28, 2004, labeling a container's content is conventional. Possessing the cited prior art's teachings, one of ordinary skill in the art would have possessed the products of the cited prior art containing ibuprofen and vitamin C, and thus, putting them in a container and labeling them would be obvious to one of ordinary skill in the art. Moreover, examiner notes that whether the minerals are labeled, or not, does not necessarily render the herein claimed invention unobvious since labeling does not lend patentable weight to the instant claims. Furthermore, examiner notes that the

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Appellant's arguments are directed to non-elected species. Such arguments are considered moot since the examinations on the merit have been directed to the elected species only.

Appellant's arguments in pages 6-7 averring discomfort reliever products and nutritional supplement products being disclosed, regulated and sold separately are not convincing. Appellant argues especially unconvincingly with regard to the prior art not disclosing any intention of supplementing nutrition; he states the prior art does not disclose nutritional supplement products: this arguments is not based in fact. As discussed above, vitamin C is a nutritional supplement regardless of whether the cited prior art expressly discloses as such because the cited prior art teaches the identical chemical structure, the properties appellant discloses and/or claims are necessarily present (See *In re Spada supra*). Furthermore, whether drug-labelling law is separate and distinct from food and nutritional supplement labelling law or not has no bearing on the patentability of the instant claims. As discussed above, labelling is conventional and thus, obvious. The law reinforces such labelling practice when the products are drugs or nutritional supplement, as evidenced in Krause and 21 CFR 201.57. Therefore, appellant's arguments, directed to the distinct and separate labelling laws, do not render the herein claimed invention unobvious. Arguments as to whether drug-labelling law is separate and distinct from food and nutritional supplement labelling law are irrelevant to the patentability of the claims.

Appellant's arguments in page 7 again directed to non-elected minerals are unconvincing. Such arguments have been addressed above. Appellant's arguments directed to non-elected species are considered moot.

Appellant's arguments in page 8 averring the problems of irregular use of essential vitamins and minerals are not convincing. Examiner notes that the instant claims are directed to a method of indication, or a method to label a container comprising the herein claimed agents. The evidence provided by the appellant hoping to illustrate a long felt need for regular use of nutritional supplements are not relevant to the herein claimed method since the instant claims are not directed to a method of regularly supplement nutritional agents. The herein claimed method is merely drawn to labeling a container, not supplementing nutritional agents. Irregularly use of essential vitamins and minerals are irrelevant to the patentability of the instant claims. Even *arguendo*, if many people irregularly use essential vitamins and minerals, appellant still fails to demonstrate how correct container labeling containing nutritional/pharmaceutical agents would produce a regular use of essential vitamins and minerals.

Appellant's arguments in pages 9 – 11 averring long felt need are not convincing. As discussed above, such arguments are directed to regularly supplementing nutritional agents, which are unclaimed limitations. Arguments directed to unclaimed limitations are considered moot. Appellant states "This recognized need for regular use of nutritional supplements, is satisfied by consuming a discomfort reliever and a nutritional supplements according to the method of Appellant's invention" [emphasis added](See page 9 of the Appeal Brief). The instant method is not directed to consuming any

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product. The instant claims are merely drawn to a method of indication or labeling a container or enclosure containing the herein claimed nutritional/pharmaceutical agents. Appellant apparently confuses a method of indication, which is instantly claimed, and a method of providing the nutritional/pharmaceutical products for regular vitamins and mineral use.

Appellant's arguments in pages 11-13 averring superior results are not convincing. The alleged benefits are not demonstrated by factual evidence. It is appellant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). There is no data presented to evaluate whether superior results are indeed present. Moreover, as discussed above, the herein presented claims are directed to a method of indication (labeling) and not a method of providing "the same discomfort relief and the same ability to self-regulate consumption of nutritional supplements". Such arguments directed towards unclaimed limitations are considered moot. Appellant states "data of superior results is shown in the elimination of half of the number of unit dose compositions and half of the number of containers required by the prior art" (See pages 12 bridging page 13 of Appeal Brief, second

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paragraph). It is unclear how the cited prior art will fail to eliminate half of the number of unit dose compositions and half of the number of containers the same way the instant invention does since the cited prior art clearly suggests the combination of ibuprofen and vitamin C in a single composition. One way to eliminate half of the number of unit dosages and containers is to combine both active agents together, which is clearly taught and suggested by the cited prior art.

Appellant's arguments in pages 13 averring omission of an element with retention of the element's function is an indicia of unobviousness are unconvincing. As discussed above, Appellant's arguments based on the cited prior art's failure to teach the elimination of half of the number of unit dose compositions and half of the number of containers are flawed as discussed in paragraph above.

Appellant's arguments in page 13 bridging page 18 averring teaching away are not convincing. Appellant's arguments that a particular vitamin cannot be replaced by another vitamin are not convincing. The cited prior art clearly teaches the elected species, namely ibuprofen and vitamin C, can be combined into a single composition. There is no teaching away present from the cited prior art. The cited prior art does not discourage one of ordinary skill in the art to combine the herein elected species together in a single composition. Moreover, the passages cited by the appellant in page 14 of the Appeal Brief with regard to Yeh et al., col. 2, lines 4-7 and 48-52, are mischaracterized by the Appellant. Appellant states "Yeh teaches away from the function of supplementing nutrition and its indication... thus, no indication of supplementing nutrition would be provided for antioxidant and/or synergistic ascorbic

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acid as part of a pain reliever product based on Yeh et al.” (See page 14 in Appeal Brief, second paragraph). The purpose of Yeh et al. to combine vitamin C and ibuprofen is treating an inflammatory disorder. Examiner would like to remind the appellant that the instant claimed method comprises the steps of combining vitamin C and ibuprofen, putting the composition in an enclosure, and labelling the enclosure for the amount and indicated use. As discussed above: 1) labeling the content is conventional as evidenced by the requirement of law in case of drugs and nutritional supplement, and 2) the label does not lend patentable weight when it does not have the functional relationship with the active agents, i.e., ibuprofen and vitamin C. Therefore, the instant claims are construed as putting the herein claimed actives, i.e., ibuprofen and vitamin C, in an enclosure, which are rendered obvious by the cited prior art.

Appellant's arguments averring, at pages 15-18, the cited prior's failure to disclose vitamin names, amount and their percent daily values as teaching away, are flawed and confusing. Firstly, as the appellant realized in page 15, second paragraph, Yeh clearly teaches the preferred antioxidants employed in Yeh's composition as ascorbic acid and its amount. Examiner notes that ascorbic acid and vitamin C are the same compound. SS Pharmaceutical and Tsunoda teach the composition comprising vitamin C and ibuprofen. Secondly, Yeh, SS Pharmaceutical, and Tsunoda are cited in the outstanding rejection under 35 USC 103(a), an obviousness rejection. In the rejection, it clearly stated that the references do not teach the labeling information (See above). However, labeling is so conventional in pharmaceutical and nutritional products, as evidenced by the teachings of Kraus and 21 CFR 201.57, one of ordinary

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skill in the art would have been motivated to put the herein claimed information in the label. Thirdly, even *arguendo*, if the cited prior art does not expressly suggest the specific information be put on the label, the instant claims are still properly rejected because, as discussed above, the label itself does not lend any patentable weight to the instant claims. Finally, when a reference does not teach certain limitations as recited, it is not teaching away: it is simply not an anticipatory reference. Teaching away must be positive statement, e.g., statements that discourage one of ordinary skill in the art to combine the herein claimed agents.

Appellant's arguments in page 17, second paragraph averring if a reference suggests that the line of development flowing from the references disclosure is unlikely to be productive of the result sought by the Appellant, it is teaching away are not convincing. Appellant further argues that the result sought by the instant claims is a method of providing a unit dose of discomfort reliever in an enclosure having indications indicating supplementing nutrition. Examiner again would like to remind the appellant that the instant claims are directed to a method of indication, or labeling, and not a method of providing a unit dose. As discussed above, 1) labeling as to content is conventional, as evidenced by the requirement of law in case of drugs and nutritional supplement, and 2) a label does not lend patentable weight when it does not have the functional relationship with the active agents, i.e., ibuprofen and vitamin C. Therefore, the instant claims are seen as combining the herein claimed actives, i.e., ibuprofen and vitamin C, in an enclosure, which steps are rendered obvious by the cited prior art.

In page 17, third paragraph bridging page 18, first paragraph appellant argues unconvincingly that indicating the herein claimed content, such as a percent daily value for a nutritional supplement in a unit dose of a discomfort reliever or consuming a unit dose of a discomfort reliever for supplementing nutrition is a result sought in the instant claims. As discussed above, 1) labeling as to content is conventional, as evidenced by the requirement of law in case of drugs and nutritional supplement, and 2) the label does not lend patentable weight when a functional relationship with the active agents does not exist, i.e., ibuprofen and vitamin C. Therefore, the instant claims are considered as a merely combination of the herein claimed actives, i.e., ibuprofen and vitamin C, in an enclosure, as act rendered obvious by the cited prior art.

Appellant's arguments in page 18-19 with regard to *Perkin-Elmer Corp.* are not convincing. As responded in the previous office action mailed January 28, 2004, in *Perkin-Elmer Corp v. Westinghouse Elec. Corp.*, the court ruled that when applying doctrine of equivalents in infringement, claims limitations cannot be ignored as insignificant or immaterial. The limitations in *Perkin-Elmer Corp v. Westinghouse Elec. Corp.*, the court ruled not to ignore is structural, functional, and operational limitations to the invention therein. In the instant case, the label, or steps of labeling, a container, which is printed material, is not a structural, functional, and operational limitation for the herein claimed active nutrition supplementing/discomfort relieving composition. See discussion with regard to *Miller* and *Gulack supra*.

Appellant's arguments in pages 19-21 averring hindsight reasoning employed by the examiner are not convincing. Appellant states "the reconstruction of the Final

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rejection takes into account more knowledge, than was within the ordinary skill at the time of invention. And it includes knowledge gleaned from Appellant's disclosure" in page 20, second paragraph. This allegation is false because the cited prior art clearly teaches the composition of ibuprofen and vitamin C, the elected species. As discussed above: labeling the content is conventional as evidenced by the requirement of law in case of drugs and nutritional supplement. Since the cited prior art teaches all the limitations recited, the alleged reconstruction in Final office action is not gleaned from appellant's disclosure.

Appellant's arguments in pages 21-22 averring for a drug product to be a nutritional supplement it must contain a vitamin or mineral intended to supplement nutrition are unconvincing. Appellant's arguments possessed a logical flaw because vitamin C is vitamin C regardless of the intended use. When one of ordinary skill in the art possesses the teachings of a vitamin C composition in the prior art, one will notice vitamin C is in this composition. When it is packaged, i.e., putting the vitamin C containing composition in an enclosure, it would be reasonable to expect to label as to amount of such vitamin C. Appellant apparently has limited his point of view to the art not intending vitamin C as a nutritional supplement but ignoring the fact that vitamin C itself is a nutritional supplement regardless of its intended use. Again, as noted above, to label as to content, and amount, thereof is conventional and reinforced by the law in the case of drug and nutritional supplement. The herein claimed method is drawn to the labeling of content within an enclosure. In view of the above explanation, the instant method of labeling is seen to be obvious.

Appellant's arguments in page 22, last paragraph bridging page 24, first full paragraph, averring the cited prior art's failure to teach the herein claimed properties of the elected species, and therefore not render obvious these steps to label the elected agents in the manner herein claimed method are not convincing. Appellant is essentially arguing the content of the label is not suggested by the cited prior art. Such arguments are not convincing in view of the discussion above through *Miller* and *Gulack supra*. The content of the label (i.e., printed materials) does not bear any patentable weight unless a function-relationship can be established between the label and the composition. In the instant case, no such relationship is seen herein.

Appellant's arguments in page 24, last paragraph states "one of ordinary skill in the art would not see vitamin C as nutritional supplement, and putting information about the amount is not mandated by law or obvious to one of ordinary skill in the art" are not convincing. Neither appellant's arguments, nor the prior art established why vitamin C is not a nutritional supplement to one of ordinary skill in the art. The well-known fact of vitamin C as a nutrient is evidenced in the law mandating the amount of vitamin C being labeled in food product. Appellant's attempt to parse the well-known properties from vitamin C is unconvincing and illogical. Supplementing nutrition is an inherent function and property present within vitamin C, whether one explicitly expresses it or not. An appellant's attempts to point out the cited prior art as not teaching the appellant's intended use of vitamin C, and then conclude that the cited prior art fails to suggest the herein claimed method. However, appellant ignores that fact that the properties and the compounds possessing these properties are inseparable. Therefore, one of ordinary

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skill in the art would be reasonably expected to consider vitamin C as a nutritional supplement, whether the cited prior art explicitly disclosed it or not. Furthermore, as discussed and pointed out numerous time above, the printed materials (label) bear no patentable weight to the claims in the instant case. In view of the above, the claims are believed to be properly rejected under 35 USC 103(a).

Appellant's arguments in page 25-26 averring the vitamin C taught in the cited prior art not being considered as nutritional supplement, and therefore unobvious to label, are as such unconvincing. As discussed above, one cannot parse out the inherent function or properties from the compound itself, because they are inseparable. The herein recited claims are directed to a method of putting a composition containing vitamin C and ibuprofen in a container and label the amount of the ingredients. Since the printed materials lend no patentable weight to the claims, the claims define no more than putting a composition containing vitamin C and ibuprofen into a container. The cited prior arts clearly disclose such composition. Putting the same into a container would be seen as conventional, and therefore obvious.

Appellant's arguments at page 27, (first paragraph) averring the cited prior art's failure to disclose the amount of vitamin C, and teaching away from the daily value of vitamin C is erroneous. The cited prior art clearly teaches the amount of vitamin C to be contained in the ibuprofen/vitamin C composition. The daily value of vitamin C, according to the instant claims, will be the same. Therefore, in view of the cited prior arts, the amount of vitamin C is clearly taught.

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Appellant's arguments at page 27 (second paragraph) bridging page 28 (first paragraph) averring the cited prior art's failure to solve the consumer's problem by putting the dosage information of ibuprofen are confusing and unconvincing. Examiner again notes that the instant method is not directed to solving consumer's problems. The instant claims are directed to a method of labeling a composition, namely, a composition containing ibuprofen and vitamin C. Appellant's claim that labeling the container will result in solving consumer's problems is not factual based. There is no evidence of record to show that it will be the case. Appellant further argues that the law does not mandate the labels indicating supplementing nutrition and/or percent daily value for drugs containing vitamins and minerals. Such arguments are unconvincing. Examiner notes that vitamin C is well-known to be nutritional supplement. When vitamin C is incorporated into a composition, one of ordinary skill in the art would have reasonably expected to label the amount of vitamin C on the outside of the container. Even *arguendo*, if there is no motivation to label the specific amount of vitamin C provided by the cited prior arts, which the Examiner does not concede, the issue would still be whether the content of the label bear any patentable weight to the instant claims. As discussed above, when the printed materials do not have a functional relationship with the product claimed, such information in the printed materials lends no patentable weight to the composition. It follows that the printed materials will also bear no patentable weight to a method of putting such label onto the container containing the same composition.

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Appellant's arguments in pages 28-30, second paragraph averring food labeling requirements not being mandatory for drug products, which are not intended to supplement nutrition, are unconvincing. These arguments, like the ones set forth earlier in the appeal brief, focus on the issue of the cited prior arts' failure to suggest a motivation to put that specific, herein claimed, information on the label. In appellant's point of view, the law does not mandate one of ordinary skill in the art to label agents as food supplement when they are not intended to be used as such. Such arguments are, in essence, directed to the issue: what should be put on the label in view of the cited prior art. Additionally, in appellant's point of view, the cited prior art does not motivate one of ordinary skill in the art to put the specific herein claimed information on the label. However, as discussed above, the content of the label lends no patentable weight to the instant claims. Therefore, the instant claims are construed as a method of putting the herein claimed composition into an enclosure. Since the cited prior art clearly provides the motivation to combine the herein elected components, one of ordinary skill in the art would considered putting the composition into a container and labeling it as obvious.

Furthermore, appellant's arguments at page 29, (second-to-last paragraph) bridging page 30, first paragraph with regard to minerals are unconvincing because those arguments are directed to the non-elected species. Arguments directed to the non-elected species are considered moot.

Appellant's arguments in page 30 (last paragraph bridging page 31, first paragraph) averring the law not mandating RDA information in labeling a drug not intended to supplement nutrition are unconvincing. These arguments are directed to

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whether the cited prior art has failed to provide motivation or suggestion to incorporate the herein specific information onto the label. As discussed above, the content of the label does not lend patentable weight to the claims. It does not matter what it is written on the label, since no functional relationship can be established between the label and the vitamin C/ibuprofen composition herein.

Appellant's arguments in page 31, second paragraph, averring Yeh's teaching away are unconvincing. Appellant attempts to employ appellant's own flawed reasoning, while ignoring Examiner's position set forth in the previous office action, thereby mischaracterizing Yeh. Such arguments have been addressed above (see response to arguments on page 15-18 with regard to Yeh).

Appellant's arguments in page 31, (last paragraph bridging page 32, second paragraph) averring the RDA amount, or the percent of vitamin C, as not being taught in the cited prior art are unconvincing. These arguments are focusing on the same issue that appellant argues with regard to the content, or the specific information on the label, not being taught by the cited prior art. As discussed above, the content of the label does not lend patentable weight to the claims. It does not matter what it is written on the label, since no functional relationship can be established between the label and the vitamin C/ibuprofen composition herein.

Appellant's arguments in page 32 (third paragraph) bridging page 33, second paragraph averring the law not mandating nutritional labeling for drug not intended to supplement nutrition are unconvincing. These arguments are directed to whether the cited prior art has failed to provide motivation, or suggestion, to incorporate the herein

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specific ingredient information onto the label. As discussed above, the content of the label does not lend patentable weight to the claims. It does not matter what it is written on the label, since no functional relationship can be established between the label and the vitamin C/ibuprofen composition herein.

Appellant's arguments in page 33, (third paragraph) averring the superior results are not convincing. In addition to the response above, Examiner also wants to point out that the alleged superior results are required to be demonstrated. Appellant fails to demonstrate such showing. Furthermore, while saving half of the number of unit dose composition could be potentially superior, these savings would not be unexpected. The instant claims are directed to a method of labeling, not a method of reminding patients or a method of regulating patient's nutrition consumption.

Appellant's arguments in page 33, (last paragraph bridging page 34, second paragraph) averring those commercial products containing minerals (as salt of the active ingredients) not providing nutritional information, are not convincing. Firstly, they are directed to non-elected nutritional supplement and therefore considered moot. Secondly, these arguments are focusing on those same issues that appellant argues repeatedly in the instant appeal brief: that the content, or the specific information on the label, is not taught by the cited prior art. As discussed above, the content of the label does not lend patentable weight to the claims. It does not matter what it is written on the label, since no functional relationship can be established between the label and the vitamin C/ibuprofen composition herein.

Appellant's arguments in page 34, second-to-last paragraph bridging page 35, second paragraph averring "it is not obvious to put information on a label regarding unintended uses of the product" are unconvincing. As discussed above, the information or the content of the label are considered printed materials. Printed materials are not to be given patentable weight if a functional activity relationship is absent (See *Miller* and *Gulack supra*). In the instant case, no such relationship is present because the pharmacological effect of the drugs will be exactly the same regardless of what is written in the label. Appellant further argues that every limitation must be considered meaningful, by citing Perkin-Elmer Corp. The arguments have been addressed above, in Examiner's response to appellant's arguments in pages 18-19.

Appellant's arguments in page 35, (third paragraph bridging page 37, line 3) averring the cited prior art's failure to teach vitamin C as a nutritional supplement are unconvincing. As discussed above, these same arguments are set forth repeatedly in the instant appeal brief. The issue of the arguments is that they are directed to the information put on the label. As discussed above, the content of the label does not lend patentable weight to the claims. It does not matter what it is written on the label, since no functional relationship can be established between the label and the vitamin C/ibuprofen composition herein.

Appellant's arguments in page 37, (second bridging page 38, first paragraph) averring the cited prior art's failure to provide motivation to label the specific herein claimed, information of vitamin C as nutritional supplements are unconvincing. As discussed above, these same arguments are set forth repeatedly in the instant appeal

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brief. The issue of these arguments is that they are directed to the information put on the label. As discussed above, the content of the label does not lend patentable weight to the claims. It does not matter what it is written on the label, since no functional relationship can be established between the label, and the vitamin C/ibuprofen composition herein.

Appellant's arguments in page 38, (second paragraph) averring Yeh's teaching away are not convincing. Attention is directed to Examiner's response to these arguments on page 15-18 of the brief with regard to Yeh.

Appellant's arguments in page 38, last paragraph averring the daily value information of vitamin C not taught by the cited prior art are unconvincing. These arguments are directed to the specific information to be put on the label. The cited prior art teaches the same amount of vitamin C as herein claimed. The content of the label, in this case, the daily value percent of vitamin C, does not lend patentable weight to the claims. It does not matter what it is written on the label, since no functional relationship can be established between the label and the vitamin C/ibuprofen composition herein.

Appellant's arguments in page 39, (second paragraph bridging page 40, second paragraph) averring the intended use of vitamin C and that specific information to be put on the label are not convincing. Vitamin C is a well-known nutrient as evidenced in the law mandating the amount of vitamin C being labeled in food product. Appellant's attempt to parse these well-known properties from vitamin C is unconvincing and illogical. Supplementing nutrition is an inherent function, or property, present within vitamin C, whether one explicitly expresses it or not. Appellant apparently attempts to

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point out the cited prior art as not teaching the appellant's intended use of vitamin C, and then conclude that the cited prior art fails to suggest the herein claimed method. However, appellant ignores that fact that the properties, and the compound possessing these properties, are inseparable. Therefore, one of ordinary skill in the art would be reasonably expected to consider vitamin C as a nutritional supplement, whether this information was disclosed in the cited prior art, or not. Furthermore, as discussed, and pointed out, numerous times above, the printed materials (label) bear no patentable weight to the claims. In the instant case, no functional relationship is established herein between the printed materials and the function of the active ingredients. In view of the above rebuttal arguments, the claims are believed to be properly rejected under 35 USC 103(a).

Appellant's arguments in page 40, (last paragraph bridging page 41) averring a Yeh's teaching away, by not disclosing vitamin function of ascorbic acid are unconvincing. As discussed in the paragraph above, supplementing nutrition is an inherent function, or property, present within vitamin C, whether one explicitly expresses it or not. Furthermore, as discussed above, the printed materials (label) bear no patentable weight to the claims in the instant case, since no functional relationship can be established herein between the printed materials and the function of the active ingredients. Since the printed materials lend no patentable weight to the claims, the claims define no more than putting a composition containing vitamin C and ibuprofen into a container. The cited prior art clearly disclose such composition. Putting the same into a container would be seen as conventional, and therefore obvious.

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Appellant's arguments in page 41, (second-to-last paragraph bridging page 42, first paragraph) averring non-elected species are considered moot. These arguments are intended to show the cited prior art's alleged failure to teach the herein claimed information to be put on the label. As discussed above, the printed materials (label) bear no patentable weight to the claims in the instant case since no functional relationship can be established herein between the printed materials and the function of the active ingredients.

Appellant's arguments at page 42 and 43 averring the claims as not drawn to a device are not convincing. As discussed above, the printed materials lend no patentable weight to the claims, and thus, it follows that the claims define no more than putting a composition containing vitamin C and ibuprofen into a container. The cited prior arts clearly disclose such composition. Putting the same into a container would be seen as conventional and therefore obvious.

For the above reasons, it is believed that the rejections should be sustained.


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Respectfully submitted,

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Art Unit 1617

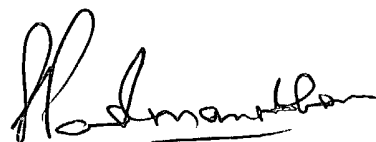
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